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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/606,369	STUELPNAGEL ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/14/03;11/10/03;2/4/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-18 and 29-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-18 and 29-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 Oct. 2003 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 40 and 44-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Ishikawa et al.(US 5,888,834).

The reference of Ishikawa et al. discloses a first array component (multiwell plate, 8); a lid (6) that includes a plurality of second array components (1) that include an array of bioactive agents (3) directly coupled to the second array component (1) and wherein the plurality of second array components (1) are aligned with a corresponding well (2) of the well plate (8). The

device includes alignment features (7,9) to facilitate alignment of the lid with the first array component (See column 9, lines 12-23).

4. Claims 39-41 and 44-47 are rejected under 35 U.S.C. 102(a) as being anticipated by Dunnington et al.(WO 98/08092).

The reference of Dunnington et al. discloses a first array component (multiwell plate, 124); a lid (102) that includes a plurality of second array components (104,108) that include an array of bioactive agents directly coupled to the second array component (104,108) and wherein the plurality of second array components (104,108) are aligned with a corresponding well (126) of the well plate (124). The device includes alignment features (116) to facilitate alignment of the lid with the first array component (See column 9, lines 34-42). The device also includes a sealant (134,128) between the lid and base forming an airtight seal (See column 9, lines 43-63).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 13-18, 29-34 and 40-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehead et al.(US 4,879,097) in view of Kolehmainen et al.(US 4,349,510).

The reference of Whitehead et al. discloses a device for forming a chamber which includes a base plate (10, 11) which holds a microtiter plate (16, 17). The device includes a lid including component ports for immobilizing array components (28 or 350). The device includes sealant (21) between the base and the lid. The device includes male/female alignment means (22). As shown in Figure 11, the chamber is connected to at least one fluid-handling device (350).

While the reference of Whitehead et al. discloses sealant, 21, so as to seal the chamber to prevent entry of stray light (See the abstract), the instant claims recite that the sealant provides an "airtight" seal.

The reference of Kolehmainen et al. discloses an optical analysis system which detects chemiluminescence. The reference of Kolehmainen et al. discloses that a light-tight seal can be maintained using an o-ring, 38 (See column 4, lines 6-27). The light-tight seal prevents external light from interfering with the detector.

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ an o-ring seal in place of seal, 21, in device of Whitehead et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result, sealing the interior of the reaction region from exterior light. Use of an o-ring as suggested by the reference of Kolehmainen et al. would inherently result in an airtight seal.

With respect to claim 14, the lid of the device of Whitehead et al. includes openings or ports which would be capable of holding a fiber optic bundle. Note claims 13 and 14 do not positively recite the bundle, only a port for immobilizing a fiber optic bundle.

With respect to claim 31, the references of Whitehead et al. and Kolehmainen et al. discloses that is it known in the art to monitor chemiluminescent or bioluminescent reactions performed in microtiter plate arrays using an array of fiber optic devices (See Column 4, lines 61-66 of Whitehead et al. and Figure 4 of Kolehmainen et al.).

In view of these teachings and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a fiber optic array in the lid structure of the reference of Whitehead et al. for the known and expected result of providing an alternative means recognized in the art to detect chemiluminescent reactions. Provision of the fiber optic and electrical

detection system would provide increased reliability over the use of photographic film which is analyzed visually and/or provide an additional analytical techniques simultaneously.

With respect to claims 37-40, the reference of Whitehead et al. also discloses that the lid (24) can include a second array component (129) that can be coated with bioactive agents (See column 9, lines 23-60 and Figures 8 and 9).

With respect to claim 41, it would have been obvious to one of ordinary skill in the art to coat each support (129) with a different bioactive agent for the known and expected result of providing a means for simultaneously performing a plurality of different luminescent immunospecific assays.

With respect to claims 42 and 43, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum density of the coated reagent based merely on the desired sensitivity of the analyte to be detected.

With respect to claim 45, while the reference of Whitehead et al. employs a 6x10 array of wells, it would have been obvious to one of ordinary skill in the art to modify the system to employ any of the standard microplate formats known in the art.

With respect to claims 46 and 47, the device includes male/female alignment means (22).

With respect to claim 48, as shown in Figure 11, the chamber is connected to at least one fluid-handling device (350).

9. Claims 36-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehead et al.(US 4,879,097) in view of Kolehmainen et al.(US 4,349,510) taken further in view of Walt et al.(US 6,327,410).

The combination of the references of Whitehead et al. and Kolehmainen et al. has been discussed above.

The above claims differ by reciting that the second array component of the lid includes arrays of bioactive agents, specifically, a substrate that includes discrete sites containing a microspheres of distinctive bioactive agents.

The reference of Whitehead et al. discloses that the disclosed supports (129) can take the form of fiber optic sensors (See column 9, lines 61-66).

The reference of Walt et al. discloses that the use of a substrate including discrete sites and a population of microspheres comprising first and second subpopulations distributed on the discrete sites wherein each subpopulation includes a distinct bioactive agent is known in the art (See column 4, line 35, to column 5, line 31).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the fiber optic sensor devices disclosed in the reference of Walt et al. in the system of the reference of Whitehead et al. for the known and expected result of providing a means recognized in the art for contacting a fiber optic sensor with a sample for analyte detection. Advantages of using the fiber optic sensor of Walt et al. over other prior art sensors include the ease of manufacture and the ability to perform high density screening of samples. Use of the system of Whitehead et al. for contacting the fiber optic sensor with a sample of analyte would allow a

plurality of samples to be simultaneously contacted with a plurality of separate fiber optic sensors while maintaining a light-tight environment.

With respect to claim 41, it would have been obvious to one of ordinary skill in the art to coat each support (129) with a different bioactive agent for the known and expected result of providing a means for simultaneously performing a plurality of different luminescent immunospecific assays.

With respect to claims 42 and 43, the reference of Walt et al. discloses the claimed density of bioactive agents (See column 5, lines 4-23).

With respect to claim 45, while the reference of Whitehead et al. employs a 6x10 array of wells, it would have been obvious to one of ordinary skill in the art to modify the system to employ any of the standard microplate formats known in the art.

With respect to claims 46 and 47, the device includes male/female alignment means (22).

With respect to claim 48, as shown in Figure 11, the chamber is connected to at least one fluid-handling device (350).

With respect to claims 36, 49 and 50, the reference of Walt et al. discloses the use of subpopulations and/or random array of microspheres.

With respect to claim 41, the reference of Walt et al. discloses list of possible bioactive agents (See column 7, line 55, to column 8, line 67) that includes peptides and nucleic acids.

Response to Arguments

10. Applicant's arguments filed 14 Oct. 2003 have been fully considered but they are not persuasive.

With respect to the combination of the references of Whitehead et al. and Kolehmainen et al., Applicants first argue that the combination is improper because the Examiner has failed to provide adequate motivation for the combination of the references. Applicants stress that the light proof barrier (21) of Whitehead et al. is to prevent entry of light into the chamber and the purpose of the o-ring of Kolehmainen et al. is to prevent detection of outside light by separate detectors contacting the reflective tape. Applicants stress that the o-ring of Kolemainen et al. is placed between the sample and the detector such that the detector does not detect stray, contaminating light from an adjacent well. As a result, Applicants conclude, at best, the reference of Kolemainen et al. would suggest placing the o-ring between the sample well and the detector of Whitehead et al. In other word, that one of ordinary skill in the art would have been motivated to place the o-ring under the sample well of Whitehead et al. or some other way between the sample well and the film, but would not have been motivated to place a sealant between the base plate and the lid forming an airtight seal.

In response to applicant's argument above, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, the primary reference of Whitehead et al. clearly discloses the use of a light-tight seal (21) so as to prevent entry of stray light between the holder (10) and cover (24). The seal employed by Whitehead et al. is characterized as a labyrinth joint (See column 5, lines 42-43). In summary, the reference of Whitehead et al. clearly discloses the use of a "light-tight

seal" between the cover (24) and the base (10). The reference of Kolehmainen et al. discloses that o-ring structure (15) is an art recognized means for making a "light-tight seal" between measuring heat (43) and well (5). In view of this disclosure, one of ordinary skill in the art would recognize that the o-ring structure of Kolehmainen et al. can be substituted for the labyrinth joint of Whitehead et al. As discussed in the M.P.E.P. at section 2144.06, substituting equivalents known for the same purpose is proper when the equivalency is recognized in the prior art. Also note "An express suggestion to substitute one equivalent component or process for another in not necessary to render such substitution obvious" (See In re Fout, 213 USPQ 532 (CCPA 1982)). In this case, one of ordinary skill in the art when presented with the prior art references discussed above would have clearly recognized that an o-ring could be used in place of a labyrinth joint for maintaining a "light-tight seal".

With respect to the combination of the references of Whitehead et al. and Kolehmainen et al., Applicants argue that the combination of the references is improper because the Examiner has failed to point to anything specific in the cited references that would suggest the motivation to combine the reference of Whitehead with the secondary reference of Kolehmainen et al. Applicants take the position that the Examiner has merely made a "common sense" argument which is impermissible.

In response, Applicants' comments are not found to be persuasive because the Examiner is of the position that the substitution of known equivalents known for the same purpose meets the requirements set forth in 35 USC 103. The prior art of record establishes that both photographic film and fiber optic detectors are known detection systems in the art of chemiluminescent detection. Note an express suggestion to substitute one equivalent

component or process for another is not necessary to render such substitution obvious (See *In re Fout*, 213 USPQ 532 (CCPA 1982)).

With respect to claim 29, Applicants argue that even if the combination of the references was proper, the claim limitations of claim 29 would not be met by the structure of the combined references. Applicants stress that the reference of Whitehead et al. fails to disclose a second array component that aligns with the first array component. Applicants state that the liquid dispensing components of Whitehead et al. are not second array components as claimed.

In response to these comments, the Examiner takes the following position. First, the liquid dispensing components are considered to meet the structure of the claimed second array component. Note the claims language of claim 29 is not commensurate with Applicants' comments as to how the second array components define over the liquid dispensers of the reference of Whitehead et al. While the two-component system that is described at page 6, lines 25-35, of the instant specification may distinguish over the liquid dispensers of the reference of Whitehead et al., claim 29 is not commensurate in scope with the system referred to in the instant specification. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the reference of Whitehead et al. also discloses the use of a second array component (129) that carries reagents which clearly provides more structure than a mere liquid dispenser.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
Primary Examiner
Art Unit 1744

WHB